patent owner and public would be better served if the restriction requirement were withdrawn or at least modified. Reconsideration or at least partial modification is respectfully requested.

Turning to the substantive rejections, Strother discloses a method and apparatus for providing therapeutic occlusions of blood vessels. The apparatus comprises an inflatable balloon 11. The walls of the inflatable balloon 11 are preferably porous (column 4, lines 9-11) so that any liquid within the balloon can readily leak out. Once the liquid leaks out, it leaves a compacted mass of filler particles which will not allow the balloon to shrink. The valve of Strother is characterized as a "leaky valve" that allows liquid to leak back out of the interior of the balloon.

Applicant respectfully submits that Strother teaches away from the present invention. Claims 1 and 11 call for a balloon that can receive and hold fluids. This is the opposite of the walls and valve of Strother. If there were any doubt on this, claim 11 has been amended to even more particularly point out and distinctly claim the present invention.

Copenhaver et al. does not cure the deficiencies of Strother. Copenhaver discloses a gastrotomy port or a one-way entrance seal for medical catheters. Thus, even if all of the teachings of Copenhaver et al. and Strother are combined, they still fail to teach the present invention set forth in claims 1 and 11.

Even if Copenhaver et al. did disclose a balloon wall capable of receiving and holding fluid (a point we disagree with supra), the combination should nevertheless fail. It is well established that references are not properly combinable or modifiable if their intended function is destroyed. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). In the present case, if one were to replace the porous balloon wall and leaky valve of Strother with fluid holding structures, then the function of the device of Strother would be destroyed. Thus the rejection based on the combination of Strother and Copenhaver should be withdrawn for this reason as well.

With respect to claim 52, this rejection also combines Strother and Copenhaver, et al. and is improper for the reasons set forth above. The Office Action further cites Dormandy Jr. et al. Claim 52 recites a valve stem with a rounded tip. Claim 52 also recites that the piercing has a bend that curves toward the stem side. None of these features are cited in any of Dormandy, Jr. et al., Strother et al. and Copenhaver et al. Thus, even if all of the teachings of these references are combined, they fail to teach the present invention as claimed in claim 52.

On page 5, the Office Action stated that a rounded tip valve stem was a matter of obvious design choice. Applicants respectfully traverse this position and note that no document

is cited in support of this assertion. It is only applicant's specification that discloses the advantages of such a structure in the context of the present invention.

In summary, there is no incentive, suggestion, reason or motivation to combine Strother, Copenhaver et al. and Dormandy Jr. et al. to arrive at the present invention. As a result, it is respectfully submitted that this case is in condition for allowance.

The dependent claims further recite patentable features, but are also allowable in light of their allowable independent claims.

Examination and reconsideration of the application as amended is requested.

Support for this amendment is clearly found in the application as originally filed. No new matter is presented.

If the Examiner comes to believe that a telephone conversation may be useful in addressing any remaining open issues in this case, the Examiner is urged to contact the undersigned attorney at 952-930-6135.

An information disclosure statement accompanies this amendment. Please charge to Deposit Account No 501921 the fee of $130.00 which is required for the timely submission of the information disclosure statement. If any additional fee is required for the timely submission of the information disclosure statement, applicants request that such fee be charged to that deposit account.

Respectfully submitted,

Registration Number	Telephone Number
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Date	
March 4, 2003	

Signature	
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Office of Intellectual Property Counsel
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Version With Markings to Show Changes Made to Specification

In the title, please change the title as follows:

Implantable Medical Balloon and Valve [Method of Making]

On page 1, after the title, please replace paragraph 1 with:

[0001] This application claims priority to U.S. provisional patent application No. 60/291,493, ["Implantable Medical Balloon and Method of Making",] filed May 15, 200[0]1 which is incorporated by reference herein.

On page 4, please replace paragraph [0019] with:

[0019] FIG.'s 4A, 4B, 4C, 4D, 4E and 4F are [is] a series of sectional views of the device of the present invention in progressive stages of manufacture.

On pages 5-6, please replace paragraph [0023] with:

[0023] The valve portion 20 is preferably molded from an elastomeric or similarly resilient material such as silicone. Such a material is advantageous because it can be pierced and remain fluid-tight after removing the piercing implement. Thus, a channel or piercing 32 is defined by the valve portion 20 and provides a path for a rigid inflation tube to follow when inserted into the balloon, thereby preventing the valve portion 20 from being damaged by the insertion of an inflation tube during an implantation operation. The piercing 32 leads from the inlet 24 to the inner chamber 72 through the valve body 22 and the valve stem 26. Preferably, the piercing 32 begins in the inlet 24 along a longitudinal axis 34, which is shared by the inlet 24, the valve body 22, and the valve stem 26. The piercing 32 continues along this longitudinal axis 34 until it reaches a predetermined location in the valve stem 26 where a curved portion or bend 36 is formed in the piercing 32, such that the piercing 32 exits the side 28 of the valve stem 26. The bend 36 is advantageous in that it enhances the ability of the silicone to close the piercing 32, thereby making the chamber 72 fluid-tight when the piercing 32 is not held open by a substantially rigid member. A close look at FIG. 1 shows how the valve stem 26 stretches and flattens during inflation. It can be seen that bend 36 of the piercing 32 forms somewhat of a flap 37 which is held closed by the pressure contained within the inner chamber [8]72.

On page 7, please replace paragraph [0029] with:

[0029] For purposes of manufacture, a skirt 54 is provided that extends downwardly from the valve body 22. The skirt 54, preferably, has an outer diameter that is smaller than

outer diameter of the valve body 22. The skirt 54 provides an attachment area so that the valve body 22 may be more readily handled during manufacturing. The smaller outer diameter of the skirt 54 creates a ridge 56 which is used to provide a visual and tactile definition of a lower extent of the valve body 22 and an upper extent of the valve skirt 54 such that the skirt 54 may be removed without removing any material from the valve body 22. The ridge 56 also creates a stop in the event that a dipping mandrel 80 (e.g. FIG.'s 4B, 4C and 4D) is used to manufacture the device 10. The mandrel 80 is preferably sized such that the skirt 54 frictionally fits within an open end of the mandrel 80. The valve body 22, however, is too large to fit within the mandrel 80. The use of the mandrel 80 will be explained in more detail below.

On page 8, please replace paragraph [0030] with:

[0030] The device 10 is completed when the balloon portion 70 is attached to, or more specifically formed on, the valve portion 20. The balloon portion 70 comprises a balloon wall 74 which is preferably integral with the cylindrical sidewall 38. The balloon wall 74 begins at approximately the ridge 56 and extends all the way over the end portion 40 and also over the opening 42. Additionally, the balloon portion includes a meniscus plug 76 which fills in the opening 42 and prevents liquid silicone solution from entering the inner chamber 72 during the dipping procedure. Once the balloon portion 70 is attached to the valve portion 20, the inner chamber 72 is defined by the cylindrical sidewall [7]38, the meniscus plug 76, the valve stem 26, and the web 44.

Marked up Version of the Claims

11. (Once Amended) A self-sealing medical balloon of unitary construction, implantable in a human body, comprising:

a cylindrical valve body having a predetermined diameter and an upper side and a lower side;

an inlet defined by said valve body lower side;

a cylindrical valve stem extending upwardly from said valve body, said valve stem having a diameter smaller than said valve body diameter;

a balloon wall adapted to receive and hold fluids, the balloon wall extending upwardly from said valve body, said balloon wall having an inner diameter, while in a deflated state, which is larger than said valve stem diameter such that an annular space exists between said balloon wall and said valve stem while said balloon is deflated, said annular space provided to relieve stress from a union of said balloon wall and said valve body when said balloon is inflated;

a piercing extending from said inlet, through said valve body and through said valve stem, into an inner chamber defined by said balloon, said piercing constructed and arranged to remain closed unless a substantially rigid member is pushed through said piercing, such as to inflate said balloon, whereby said piercing recloses after said member is withdrawn, thereby preventing a fluid from escaping from said inner chamber.